

Notice of Allowability

Application No.

09/498,305

Examiner

William W. Moore

Applicant(s)

ENSLEY, BURT D.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment filed 15 September 2003 and the interview of 8 June 2004.
2. ☒ The allowed claim(s) is/are 1,2,5 and 9-14.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 16 July 2001.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 08 June 2004 .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Cancel claims 26-37.

Rewrite claim 12 thus:

12. (Amended) The method of claim 1 wherein the tropoelastin or lysyl oxidase has been mixed with other materials selected from the group consisting of polymers, emulsifiers, oils, ~~perfumes, proteins,~~ polysaccharides, ~~nucleic acids,~~ microfibrils, antimicrobial agents, adhesive agents, and protease inhibitors.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Brenda Herschbach Jarrell on June 8, 2004.

The following is an examiner's statement of reasons for allowance:

The above examiner's amendment deletes the new claims 26-37, which raise an issue of indefinite description where there is no specific, unique, sequence with which a claimed percentage identity might be compared, and clarifies claim 12 by removing "proteins" and "nucleic acids", which are redundant with another term, "polymers," and removing "perfumes", compounds extraneous to a method for promoting the healing of a skin wound.

Applicant's Amendments of claims 1 and 13 in the Response filed September 15, 2003, clarify the intended subject matters and Applicant's arguments in the Response are persuasive in establishing that Bedell-Hogan et al. teach no comparison of efficacy of lysyl oxidase activity that adequately contrasts the cross-linking of recombinantly-produced elastin monomers, which they had prepared, and the cross-linking of native elastin monomers. Applicant notes instead that Bedell-Hogan et al. had used insoluble,

Art Unit: 1652

already cross-linked, elastin to produce results depicted in their Figure 1. Applicant's arguments are also persuasive in establishing that the closest prior art, Weiss et al., U.S. Patent 6,277,622, of record, does not contemplate the application to a wound of tropoelastin that lacks cross-linking together with lysyl oxidase where Weiss et al. fail to distinguish between the use of a cross-linked substrate for lysyl oxidase, or an incompletely or partially cross-linked substrate, and the use of tropoelastin that, according to claims 1 and 13, "has not previously been cross linked" in teaching the treatment of a wound by adding the enzyme together with the substrate. Thus the prior art of record cannot be considered to suggest or to render obvious the claimed invention. Indeed, a survey of U.S. Patents issued on applications with priority dates before the filing date of the instant application, nine of which are made of record herewith, as well as pre-grant publications of U.S. patent applications with priority dates before the filing date of the instant application, that discuss in some way the activity of lysyl oxidase on elastin substrates, including tropoelastin, and also disclose various medical uses of elastins, including tropoelastin, including topical application in the treatment of a skin condition, fail to suggest that tropoelastin should be prepared separately from the enzyme and that both should then be applied, concurrently or sequentially, to treat a skin condition, such as a wound.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1652

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
June 8, 2004



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SUPERVISORY PATENT EXAMINER
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